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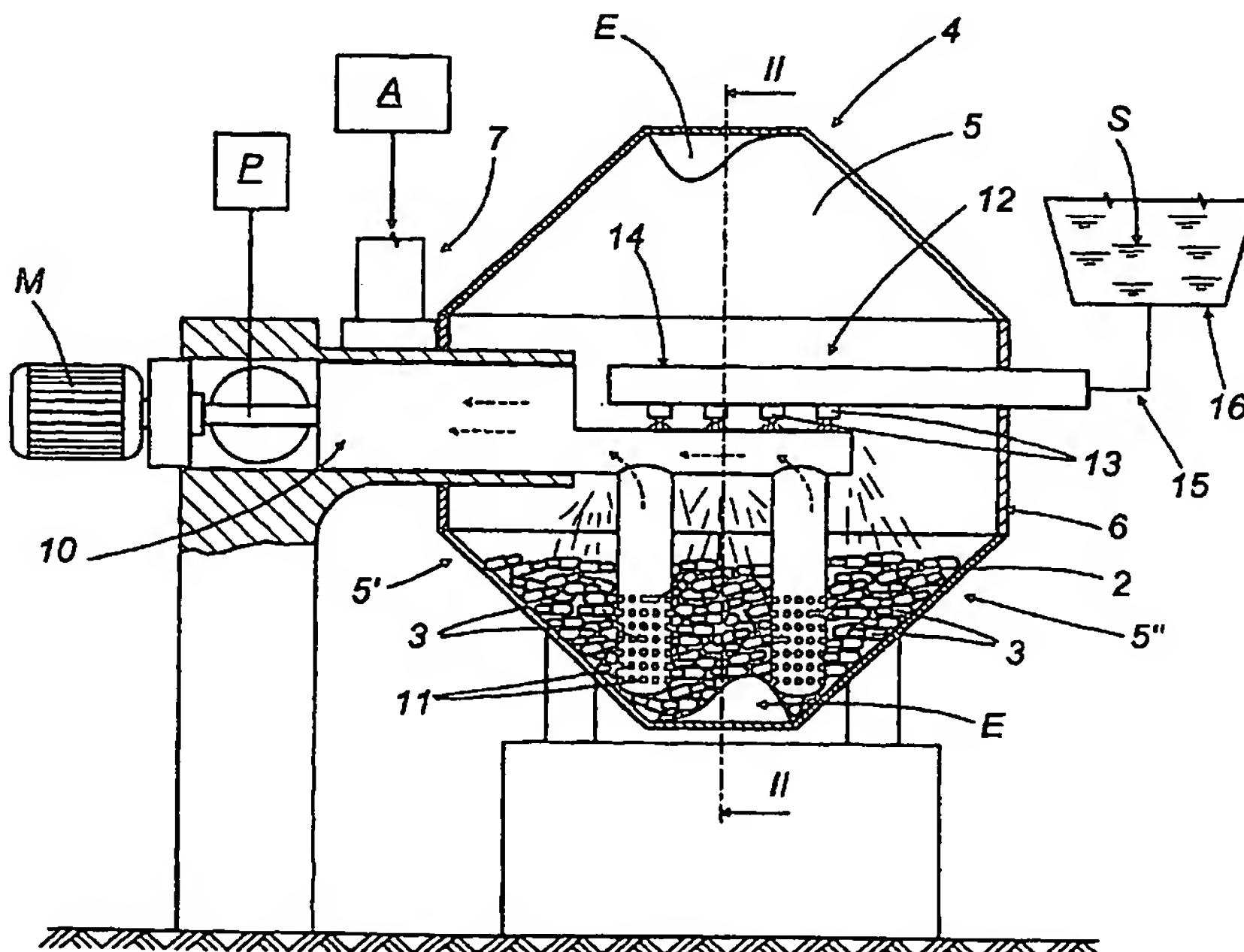
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(54) Title: A METHOD FOR A SEALING TREATMENT FOR HARD GELATINE CAPSULES



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(57) Abstract: A method for a sealing treatment for hard gelating capsules (3) involves the implementation of a step of coating the capsules (3) by spraying them with a sealing substance (S) and a step of drying the capsules (3), said steps of coating and drying being carried out simultaneously and continuously in a rotary drum (4) containing a mass (2) of such capsules (3).

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

DescriptionA method for a sealing treatment for hard gelatine capsulesTechnical Field

The present invention relates to a method for a sealing treatment for hard gelatine capsules.

More specifically, the present invention relates to a method for sealing hard gelatine capsules, each consisting of a lid which is connected telescopically, and partially overlapping, with a capsule body, to create a permanent and stable fastening between the lid and the capsule body, to prevent the exit of the material contained in the capsules due to sudden and unwanted removal of the lids from the respective capsule bodies, or to ensure that the capsule are not subject to dangerous adulteration following undetectable fraudulent tampering with the lid - capsule body connection.

In particular, the present invention is advantageously used to seal hard gelatine capsules in the pharmaceutical sector, to which the following description refers, without limiting the scope of the present invention, containing liquid or powdered materials with active ingredients having a pharmacological action, and sometimes mixed with excipients.

20

Background Art

At present, there are various known methods for fastening lids to hard gelatine capsule bodies. The best known involves a mechanical type of fastening by, for example, snapping a ring-shaped projection on the capsule lid into a matching ring-shaped recess in the capsule body.

This fastening is complicated to make, but above all does not always remain perfectly stable, in particular when the capsules are handled during capsule packaging operations.

30 In particular, in a machine which packages the capsules into blister packs, capsules are normally fed along substantially vertical tubular pipes, and it has been noticed that the use of

5 capsules with a lid - body fastening of the above-mentioned snap-on type results in a significant increase in blister packer down times, needed to clear the capsule downfeed pipes towards the blister web when they are blocked by individual lids which have come off the relative capsule bodies and jammed crossways in the pipes.

10 When the snap-on fastening method is used, the capsules can easily be subject to alterations, in particular as regards their contents, due to the ease with which the capsule can be fraudulently opened by removing the lid from the capsule body and without said fraudulent opening being subsequently detected and highlighted by the normal control devices.

15 Moreover, since this type of fastening is not watertight, it is normally used to fasten lids to capsule bodies for capsules containing powdered materials, whilst it obviously cannot be used effectively for capsules which are filled with liquids. For these capsules, different methods of sealing the capsule lid to the capsule body are used, such as for, for example, the method described in United States patent No. 4.820.364, which consists in 20 spraying the ready filled capsules, as they pass along a first conveyor, with an aqueous adhesive fluid substance so that the substance makes contact with the zone at which the lid partially overlaps the body of each capsule. During a subsequent step, the capsules are first subjected to a washing operation to eliminate 25 excess portions of the adhesive substance, then, arranged on a second conveyor, they are subjected to a heating step, to create a permanent seal between the lids and capsule bodies.

30 This fastening method is tamper-resistant, but has the significant disadvantage of being complicated, as well as requiring relatively long periods of time for its implementation. Moreover, if said capsule washing step is not carried out rapidly after spraying the adhesive substance, some capsules may stick to 35 one another due to the effect of the excess adhesive substance not yet eliminated by washing, thus creating products which must be rejected.

The above-mentioned disadvantage may be overcome by a known lid - capsule body fastening method in which the capsules are

immersed in a sealing bath, made using a sealing substance consisting in particular of an aqueous ethanol mixture, then dried.

According to this known solution, the capsules are immersed 5 in the sealing substance by means of a rotary drum which is partially immersed in the substance and has radial seats, each housing a single capsule positioned by downfeed, one after another, from a hopper located above the drum. The capsules are then ejected from the seats, again one at a time, by air jets 10 which also cause the capsules to drop onto roller conveyor belts located in a drying chamber.

As can easily be imagined, with the latter method, since it involves treating the capsules one at a time, the number of capsules which can be processed in the unit of time is limited, 15 and cannot be increased even if the speed of rotation of the drum with the seats is considerably increased. Therefore, it cannot satisfy current high-speed production requirements.

Moreover, since the seats in the drum have precise dimensions, each time a capsule of a different size is to be 20 processed, the entire drum must be substituted with another drum having seats suited to the shape of the new capsules to be treated.

#### Disclosure of the Invention

25 The aim of the present invention is to provide a method for a sealing treatment for hard gelatine capsules, which overcomes the above-mentioned known disadvantages.

In particular, the aim of the present invention is to provide a method for a sealing treatment for hard gelatine 30 capsules, whose use makes it possible to process a very large quantity of capsules in the unit of time, creating an optimum seal on the capsules which is also tamper-resistant.

Another aim of the present invention is to provide a method for a sealing treatment for hard gelatine capsules using sealing 35 substances without organic solvents or ethanol.

Accordingly, the present invention provides a method for a sealing treatment for hard gelatine capsules comprising a step of

coating the capsules by spraying them with a sealing substance and a step of drying the capsules. The method is characterised in that the coating and drying steps are carried out simultaneously and continuously in a rotary drum containing a mass of said capsules.

5 Preferably, inside the drum, the coating step is carried out by means of at least one nozzle for spraying the sealing substance and the drying step is carried out by a ventilation unit comprising at least one pipe for the free infeed of an air flow into the drum and at least one pipe to carry the air out of the  
10 drum.

15 The present invention is now described with reference to the accompanying drawings, which illustrate a preferred embodiment without limiting the scope of application of a device for a sealing treatment for capsules using the method according to the present invention and in which:

20 - Figure 1 is a side view, partly in cross-section and with some parts cut away for clarity, of a preferred embodiment of the device which implements the method according to the present invention; and

25 - Figure 2 is a vertical cross-section 2 - 2 of the device illustrated in Figure 1;

30 - Figure 3 is an enlarged schematic front view of a capsule sealed using the method according to the present invention.

With reference to the accompanying drawings, the numeral 1  
25 indicates a device for the sealing treatment for a mass 2 of hard gelatine capsules 3 of the known type (one of which is illustrated in Figure 3), already containing a preset quantity of powdered or liquid material containing an ingredient with pharmacological action, sometimes mixed with excipients, each consisting of a lid  
30 3' attached telescopically and in such a way that it partially overlaps a capsule body 3''.

35 The device 1 is of the known type described in European Patent No. 131.152 B1 in the name of G. S. di Scipioni e Giogoli S.n.c., the disclosure of which is incorporated herein by reference, and comprises a hollow drum 4, which is rotatably supported by a fixed framework. Driven by known motor means M, the drum rotates about a horizontal axis and is known as the

"Pellegrini type drum" and hereinafter will be referred to with the term "drum".

5 The capsules 3 which form the mass 2 to be treated are fed through a door 6 which opens into the cavity 5 inside the rotary drum 4, which is substantially cylindrical and has deflecting helical fins E with truncated cone shaped end portions 5' and 5''.

As illustrated in Figures 1 and 2, the device 1 comprises a capsule 3 ventilation unit 7, which in turn comprises a channel 8 for the inflow and diffusion of air, from a source A, inside the 10 cavity 5 and a pair of substantially hollow tubular bodies 9 with a cross-section which is preferably elliptical, which communicate with a suction pump P by means of a manifold 10 coaxial with the drum 4 and which extend in cantilever style, parallel with one another, transversally and radially to the manifold 10.

15 The bodies 9 and the manifold 10 rotate relative to the horizontal axis of the drum 4 and their angular position can be adjusted: preferably as indicated in Figure 2, during drum 4 rotation, the bodies 9 are advantageously positioned at a given angle  $\alpha$  to the vertical, depending, for example, on the speed of 20 rotation of the drum 4.

Again in Figures 1 and 2, the hollow tubular bodies 9 are partially immersed in the mass 2 of capsules 3 and their closed ends are fitted with a matrix of suitable holes 11, through which the air from the source A fed into the drum 4 through the channel 25 8, is sucked towards the outside of the cavity 5 by the pump P.

In addition to the content of European Patent No. 131.152 B1 registered by G. S., the cavity 5 in the drum also contains a unit 12 consisting of spray nozzles 13, designed to spray and diffuse over the whole mass 2 of capsules 3 a liquid mixture of a sealing substance S, so as to coat the capsules 3 with the substance S and, in particular, to form a seal between the lids 3' and the capsule bodies 3'' of the capsules 3 in the mass 2.

30 The unit 12 comprises a rod 14 which is connected to a supply circuit 15 for the sealing substance S contained in a tank 16 on the outside of the drum 4, extending in practice over the mass 2 inside the drum 4, through a suitable cavity in the door 6, and fitted with the nozzles 13 in series.

The unit 12 is preferably mounted on a structure of the known type and not illustrated, removable from and relative to the drum 4 so that, when the drum 4 is stationary, the rod 14 supporting the nozzles 13 can be removed from inside the drum 4, 5 for example, during infeed of the capsules 3 through the door 6 and/or during normal drum 4 maintenance/cleaning operations and/or during normal nozzle 13 maintenance/cleaning operations.

In practice, once the mass 2 of capsules 3 has been fed into the drum 4 and after the rod 14 with the nozzles 13 has been 10 positioned so that it is suspended inside the drum 4 over the mass 2, drum 4 rotation is activated with simultaneous activation of substance S feed to the nozzles 13 and air infeed from the source A.

Therefore, inside the rotary drum 4, the entire mass 2 of 15 capsules 3 are continuously coated with the substance S sprayed by the nozzles 13 and simultaneously dried by the continuous air flow which circulates freely inside the drum 4 and is then sucked out by the pump P through the holes 11 in the bodies 9.

In this way, it is possible to obtain an optimum, tamper-resistant seal on the capsules 3 using a rapid, safe and 20 economical sealing treatment which, because it does not involve any interruptions between the spraying and drying steps, does not allow capsules to stick to one another.

As regards the sealing substance S used, experimental 25 testing has provided optimum sealing results for large masses of capsules 3 using aqueous polymer mixtures as the substance S, sometimes with added plasticisers and/or non-stick agents. Optimum results can also be obtained using a sugary syrup as the substance S.

Further experimental tests have also shown that using some 30 specific types of polymers, such as polyvinyl acetophthalate, or hydroxypropyl methyl cellulose phthalate, or cellulose acetophthalate, or copolymers of metacrylic acid, or type A and B 35 copolymers of ammonium metacrylate, it is possible to obtain sealed capsules whose disintegration in the human body occurs at different rates according to the nature and/or quantity of the polymer with which the capsules are sealed. In other words, the

sealed capsules have properties for the controlled release of the active ingredient with pharmacological effect (that is to say, gastro-resistant properties).

Using the sealing method disclosed, it is possible to 5 obtain, in particular, hard gelatine capsule which are noticeably more resistant to mechanical stresses, for example those caused by operations involved in packaging the capsules in blister packers.

Moreover, since during the treatment the entire outer 10 surface of each capsule is coated with the sealing substance, its capacity for sliding is significantly increased.

Finally, with a drum which comes in a single size, the sealing treatment can be applied to capsules with dimensions which may vary greatly, allowing significant economic savings.

Claims

1. A method for a sealing treatment for hard gelatine capsules (3) comprising a step of coating the capsules (3) by spraying them with a sealing substance (S) and a step of drying the capsules (3); the method being characterised in that the coating and drying 5 steps are carried out simultaneously and continuously inside a rotary drum (4) containing a mass (2) of said capsules.
2. The method according to claim 1, characterised in that, inside the drum (4), the coating step is carried out using at 10 least one nozzle (13) for spraying the sealing substance (S) and in that the drying step is carried out by a ventilation unit (7) comprising at least one channel (8) for the infeed of an air flow which circulates freely inside the drum (4) and at least one pipe (9, 11) which carries the air out of the drum (4). 15
3. The method according to claim 2, characterised in that the outlet pipe (9, 11) comprises at least one hollow body (9), suspended inside the drum (4) and over the mass (2) of capsules (3), and having holes (11) which allow the air to leave the drum 20 (4).
4. The method according to any of the claims from 1 to 3, characterised in that the sealing substance (S) comprises aqueous polymer mixtures. 25
5. The method according to any of the claims from 1 to 3, characterised in that the sealing substance (S) comprises aqueous mixtures of polymers with the addition of plasticising and/or non-stick substances. 30
6. The method according to any of the claims from 1 to 3, characterised in that the sealing substance (S) comprises aqueous mixtures of polymers with gastro-resistant properties.

7. The method according to any of the claims from 1 to 3, characterised in that the sealing substance (S) comprises a sugary syrup.

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FIG. 1

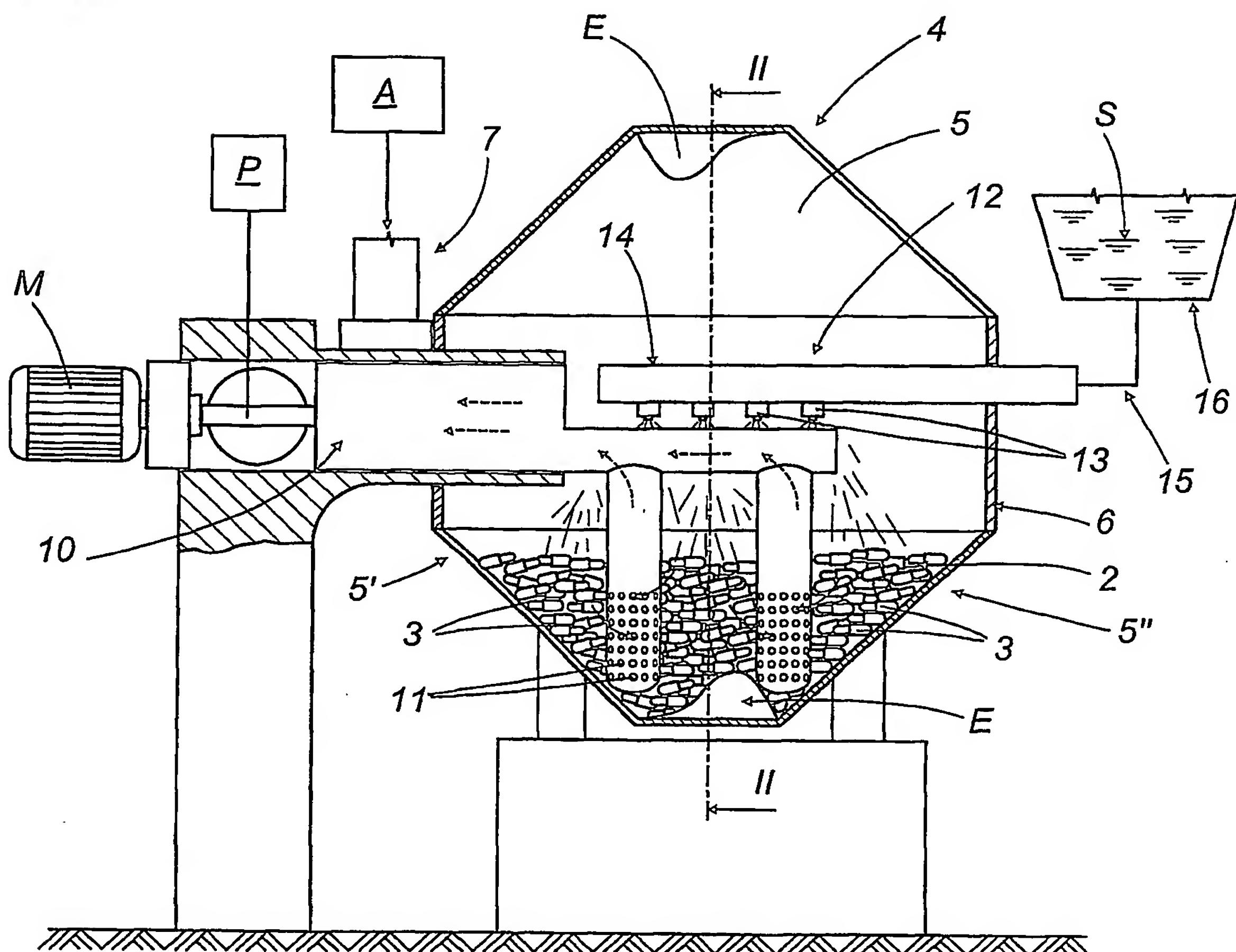


FIG. 2

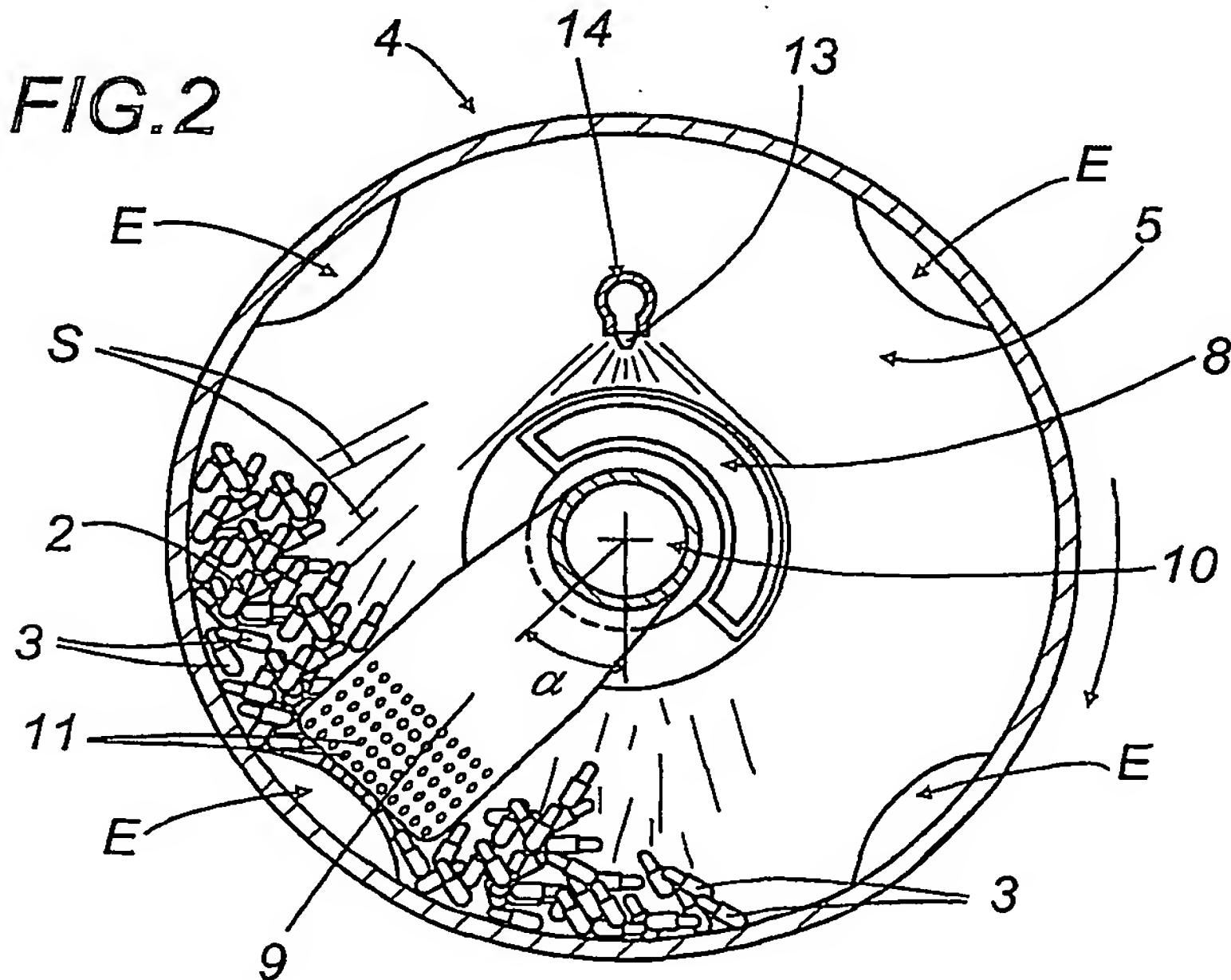
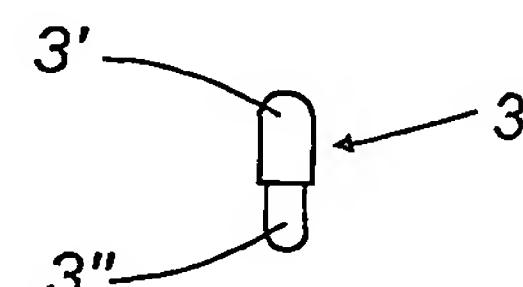


FIG. 3



## INTERNATIONAL SEARCH REPORT

Int'l	Application No
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A. CLASSIFICATION OF SUBJECT MATTER	
IPC 7	A61J3/07

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED	
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Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT	
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Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 152 517 A (WARNER LAMBERT CO) 28 August 1985 (1985-08-28)	1,2
Y	page 19, line 33 -page 20, line 4 page 20, line 18 - line 21; figures ---	3
Y	EP 0 131 152 A (SCIPIONI & GIOGOLI SNC) 16 January 1985 (1985-01-16) cited in the application page 4, line 20 -page 5, line 6; figures ---	3
A	GB 956 300 A (ORGANON LABOR LTD) 22 April 1964 (1964-04-22) page 1, line 40 - line 67 ---	1-7
A	US 5 617 710 A (GOOSSENS FRANCIS ET AL) 8 April 1997 (1997-04-08) column 4, line 66 -column 5, line 30; figures ---	4,5,7
		-/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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nal Application No  
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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 37 04 992 A (WARNER LAMBERT CO) 24 September 1987 (1987-09-24) claim 8; figures ----	4,5,7
A	CH 679 640 A (MARIGEN SA) 31 March 1992 (1992-03-31) column 1, line 39 - line 44 ----	6

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No  
PCT/IB 02/00240

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
EP 0152517	A	28-08-1985	US	4656066 A	07-04-1987
			AT	38326 T	15-11-1988
			AU	566690 B2	29-10-1987
			AU	2722984 A	29-08-1985
			BG	44702 A3	16-01-1989
			BR	8402129 A	10-12-1985
			CA	1215511 A1	23-12-1986
			DE	3474910 D1	08-12-1988
			EP	0152517 A1	28-08-1985
			ES	532101 D0	16-02-1985
			ES	8503246 A1	01-06-1985
			IN	161491 A1	12-12-1987
			JP	60176656 A	10-09-1985
			KR	9107956 B1	04-10-1991
			MX	161142 A	07-08-1990
			PH	22724 A	28-11-1988
			YU	77684 A1	31-12-1987
EP 0131152	A	16-01-1985	IT	1206686 B	27-04-1989
			DE	3465429 D1	24-09-1987
			EP	0131152 A1	16-01-1985
GB 956300	A	22-04-1964	NONE		
US 5617710	A	08-04-1997	EP	0765150 A1	02-04-1997
			JP	10501718 T	17-02-1998
			WO	9534269 A1	21-12-1995
DE 3704992	A	24-09-1987	CH	674800 A5	31-07-1990
			BE	1000456 A3	13-12-1988
			BR	8701489 A	05-01-1988
			CA	1295246 A1	04-02-1992
			CN	87101814 A , B	30-12-1987
			DE	3704992 A1	24-09-1987
			EG	18330 A	30-10-1992
			FR	2595568 A1	18-09-1987
			GB	2187703 A , B	16-09-1987
			IT	1207335 B	17-05-1989
			JP	1904697 C	08-02-1995
			JP	6034806 B	11-05-1994
			JP	62270160 A	24-11-1987
CH 679640	A	31-03-1992	CH	679640 A5	31-03-1992

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